

(b) You must inform the employee that he or she has 72 hours from the time you provide this notification to him or her to request a test of the split specimen.

(c) You must tell the employee how to contact you to make this request. You must provide telephone numbers or other information that will allow the employee to make this request. As the MRO, you must have the ability to receive the employee's calls at all times during the 72 hour period (*e.g.*, by use of an answering machine with a "time stamp" feature when there is no one in your office to answer the phone).

(d) You must tell the employee that if he or she makes this request within 72 hours, the employer must ensure that the test takes place, and that the employee is not required to pay for the test from his or her own funds before the test takes place. You must also tell the employee that the employer may seek reimbursement for the cost of the test (see § 40.173).

(e) You must tell the employee that additional tests of the specimen (*e.g.*, DNA tests) are not authorized.

§ 40.155 What does the MRO do when a negative or positive test result is also dilute?

(a) When the laboratory reports that a specimen is dilute, you must, as the MRO, report to the DER that the specimen, in addition to being negative or positive, is dilute.

(b) You must check the "dilute" box (Step 6) on Copy 2 of the CCF.

(c) When you report a dilute specimen to the DER, you must explain to the DER the employer's obligations and choices under § 40.197, to include the requirement for an immediate recollection under direct observation if the creatinine concentration of a negative-dilute specimen was greater than or equal to 2mg/dL but less than or equal to 5mg/dL.

(d) If the employee's recollection under direct observation, in paragraph (c) of this section, results in another negative-dilute, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF documentation shows that the recollection was directly ob-

served as required, report this result to the DER as a negative-dilute result.

(3) If CCF documentation indicates that the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41952, Aug. 9, 2001; 68 FR 31626, May 28, 2003; 69 FR 64867, Nov. 9, 2004; 73 FR 35971, June 25, 2008]

§ 40.157 [Reserved]

§ 40.159 What does the MRO do when a drug test result is invalid?

(a) As the MRO, when the laboratory reports that the test result is an invalid result, you must do the following:

(1) Discuss the laboratory results with a certifying scientist to determine if the primary specimen should be tested at another HHS certified laboratory. If the laboratory did not contact you as required by §§ 40.91(e) and 40.96(c), you must contact the laboratory.

(2) If you and the laboratory have determined that no further testing is necessary, contact the employee and inform the employee that the specimen was invalid. In contacting the employee, use the procedures set forth in § 40.131.

(3) After explaining the limits of disclosure (see §§ 40.135(d) and 40.327), you must determine if the employee has a medical explanation for the invalid result. You must inquire about the medications the employee may have taken.

(4) If the employee gives an explanation that is acceptable, you must:

(i) Place a check mark in the "Test Cancelled" box (Step 6) on Copy 2 of the CCF and enter "Invalid Result" and "direct observation collection not required" on the "Remarks" line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that no further action is required unless a negative test result is required (*i.e.*, pre-employment, return-to-duty, or follow-up tests).

(iii) If a negative test result is required and the medical explanation concerns a situation in which the employee has a permanent or long-term medical condition that precludes him or her from providing a valid specimen,

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as the MRO, you must follow the procedures outlined at §40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

(5) If the employee is unable to provide an explanation and/or a valid prescription for a medication that interfered with the immunoassay test but denies having adulterated the specimen, you must:

(i) Place a check mark in the "Test Cancelled" box (Step 6) on Copy 2 of the CCF and enter "Invalid Result" and "direct observation collection required" on the "Remarks" line.

(ii) Report to the DER that the test is cancelled, the reason for cancellation, and that a second collection must take place immediately under direct observation.

(iii) Instruct the employer to ensure that the employee has the minimum possible advance notice that he or she must go to the collection site.

(6) When the test result is invalid because pH is greater than or equal to 9.0 but less than or equal to 9.5 and the employee has no other medical explanation for the pH, you should consider whether there is evidence of elapsed time and increased temperature that could account for the pH value.

(i) You are authorized to consider the temperature conditions that were likely to have existed between the time of collection and transportation of the specimen to the laboratory, and the length of time between the specimen collection and arrival at the laboratory.

(ii) You may talk with the collection site and laboratory to discuss time and temperature issues, including any pertinent information regarding specimen storage.

(iii) If you determine that time and temperature account for the pH value, you must cancel the test and take no further action, as provided at paragraph (a)(4) of this section.

(iv) If you determine that time and temperature fail to account for the pH value, you must cancel the test and direct another collection under direct observation, as provided at paragraph (a)(5) of this section.

(b) You may only report an invalid test result when you are in possession

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of a legible copy of Copy 1 of the CCF. In addition, you must have Copy 2 of the CCF, a legible copy of it, or any other copy of the CCF containing the employee's signature.

(c) If the employee admits to having adulterated or substituted the specimen, you must, on the same day, write and sign your own statement of what the employee told you. You must then report a refusal to test in accordance with §40.163 .

(d) If the employee admits to using a drug, you must, on the same day, write and sign your own statement of what the employee told you. You must then report that admission to the DER for appropriate action under DOT Agency regulations. This test will be reported as cancelled with the reason noted.

(e) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for the same reason as reported for the first specimen, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF review indicates that the recollection was directly observed as required, document that the employee had another specimen with an invalid result for the same reason.

(3) Follow the recording and reporting procedures at (a)(4)(i) and (ii) of this section.

(4) If a negative result is required (i.e., pre-employment, return-to-duty, or follow-up tests), follow the procedures at §40.160 for determining if there is clinical evidence that the individual is an illicit drug user.

(5) If the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

(f) If the employee's recollection (required at paragraph (a)(5) of this section) results in another invalid result for a different reason than that reported for the first specimen, as the MRO, you must:

(1) Review the CCF to ensure that there is documentation that the recollection was directly observed.

(2) If the CCF review indicates that the recollection was directly observed

as required, document that the employee had another specimen with an invalid result for a different reason.

(3) As the MRO, you should not contact the employee to discuss the result, but rather direct the DER to conduct an immediate recollection under direct observation without prior notification to the employee.

(4) If the CCF documentation indicates that the recollection was not directly observed as required, do not report a result but again explain to the DER that there must be an immediate recollection under direct observation.

(g) If, as the MRO, you receive a laboratory invalid result in conjunction with a positive, adulterated, and/or substituted result and you verify any of those results as being a positive and/or refusal to test, you do not report the invalid result unless the split specimen fails to reconfirm the result(s) of the primary specimen.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008; 75 FR 49863, Aug. 16, 2010]

§ 40.160 What does the MRO do when a valid test result cannot be produced and a negative result is required?

(a) If a valid test result cannot be produced and a negative result is required, (under § 40.159 (a)(5)(iii) and (e)(4)), as the MRO, you must determine if there is clinical evidence that the individual is currently an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation. In addition, if appropriate, you may also consult with the employee's physician to gather information you need to reach this determination.

(b) If you do not personally conduct the medical evaluation, as the MRO, you must ensure that one is conducted by a licensed physician acceptable to you.

(c) For purposes of this section, the MRO or the physician conducting the evaluation may conduct an alternative test (e.g., blood) as part of the medically appropriate procedures in determining clinical evidence of drug use.

(d) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report this to the employer as a negative test result with

written notations regarding the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted in another invalid result for the same reason, as appropriate) and for the determination that no signs and symptoms of drug use exist.

(1) Check "Negative" (Step 6) on the CCF.

(2) Sign and date the CCF.

(e) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the employer as a cancelled test with written notations regarding the results of the medical examination. The report must also state why the medical examination was required (i.e., either the basis for the determination that a permanent or long-term medical condition exists or because the recollection under direct observation resulted in another invalid result for the same reason, as appropriate) and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purpose of an actual negative test result (i.e., the employer is not authorized to allow the employee to begin or resume performing safety-sensitive functions, because a negative test result is needed for that purpose).

[73 FR 35972, June 25, 2008]

§ 40.161 What does the MRO do when a drug test specimen is rejected for testing?

As the MRO, when the laboratory reports that the specimen is rejected for testing (e.g., because of a fatal or uncorrected flaw), you must do the following:

(a) Place a check mark in the "Test Cancelled" box (Step 6) on Copy 2 of the CCF and enter the reason on the "Remarks" line.

(b) Report to the DER that the test is cancelled and the reason for cancellation, and that no further action is required unless a negative test is required (e.g., in the case of a pre-employment, return-to-duty, or follow-up test).